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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,298	03/29/2004	Matthieu Guitton	AUR-2001US01	1803

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,298	GUITTON ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed April 15, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 2-9 under 35 U.S.C. 112, first paragraph (scope enablement) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 1 and 4-9 under 35 U.S.C. 112, first paragraph (scope enablement) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Tabuchi et al. (2002) in view of Donovan (U.S.Patent No. 6,265,379 B1) is being **maintained** for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to exclude canceled claims.

Response to Arguments

Applicants' arguments filed April 15, 2008 have been fully considered but they are not persuasive. Applicants argue that Tabuchi et al. do not teach that the ischemic/reperfusion model that they used cause a damage to nerve cells by

excitotoxicty or that NMDA antagonists used in their work exerted their effect by blocking NMDA receptors. Applicants further argue that Tabuchi et al. teach against the present invention by teaching that ketamine is effective in their system by working via a pathways other than NMDA-receptor inhibition. This is not found to be persuasive because instant method is drawn to a method step of administration of the active agent, ketamine. Therefore, the employment of the ketamine is at issue. Tabuchi et al. teach that ketamine is effective providing protection against ischemia reperfusion injury to the cochlea. Applicants' argument that ketamine is effective in Tabuchi et al. by working via a pathways other than NMDA-receptor inhibition, does not change the same compound, ketamine is taught to have the relevant chemical/physical characteristic of having the protection against ischemia reperfusion injury to the cochlea. The mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effect (protection against ischemic injury to the cochlea) which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Applicants argue that Tabuchi et al. do not teach that ketamine can be used for the treatment of disease states induced by cochlear excitotoxicty and treated by NMDA-receptor inhibition as presently claimed. This is not found to be persuasive because that Tabuchi et al's conclusion that NMDA receptor antagonism alone did not protect the cochlear from the injury does not completely eliminate the physical/chemical

characteristic of the NMDA receptor antagonism of ketamine itself. In this case, the same active substance is taught by the reference. Therefore, the same active substance taught by the reference would have the properties of NMDA receptor antagonistic activity. It discuses the same chemical compound, ketamine. It must possess the NMDA antagonistic property as claimed because it is one and the same compound. Applicants argue that Donovan does not provide an unambiguous relation to the disorder "tinnitus" since only a small portion of animals suffering from hypoxia ischemia model as used by Donovan also exhibit tinnitus. This is not found to be persuasive because Donovan teaches that tinnitus, particularly inner ear tinnitus is due to cochlear nerve dysfunction. Therefore, it would have been obvious to one of ordinary skill in the art to employ ketamine for the treatment of tinnitus induced by cochlear excitotoxicty provoked by ischemia because Tabuchi et al. teach the protective effect of ketamine in cochlear injury/dysfunction due to ischemic-reperfusion and because tinnitus is a disorder of cochlea as taught by Donovan. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabuchi et al. (2002) in view of Donovan (U.S.Patent No. 6,265,379 B1).

Tabuchi et al. teach that ketamine has protective effect against cochlear dysfunction induced by transient ischemia. (title). Tabuchi et al. teach that ketamine has protective effect against ischemia-reperfusion injury of the cochlea. (abstract). Tabuchi et al. teach that ketamine was administered intravenously. (page 45, left-hand column #1).

Tabuchi et al. do not expressly teach the treatment of tinnitus in human, site of local administration set forth in claims 5 and 6, and duration of cochlear excitotoxicty set forth in claims 7-9.

Donovan teaches that tinnitus, particularly inner ear tinnitus is due to cochlear nerve dysfunction. (column 2, lines 54-55). Donovan teaches local administration for the treatment of tinnitus includes injection. (column 5, lines 62-67).

It would have been obvious to one of ordinary skill in the art to employ ketamine for the treatment of tinnitus induced by cochlear excitotoxicty provoked by ischemia because Tabuchi et al. teach the protective effect of ketamine in cochlear injury/dysfunction due to ischemic-reperfusion and because tinnitus is a disorder of cochlea as taught by Donovan. One would have been motivated to employ ketamine for the treatment of tinnitus in order to achieve an expected benefit of protection against cochlear damage due to ischemic-reperfusion resulting tinnitus well known condition due to cochlear dysfunction by Donovan. Further, it would have been obvious to one of

ordinary skill in the art to employ ketamine for the treatment of tinnitus in human because it is next logical step next to Tabuchi et al's successful ketamine treatment against protection of cochlear injury due to ischemic-reperfusion. One would have been motivated to employ ketamine in human suffering from tinnitus in order to achieve an expected benefit of protection of cochlea in vivo experimentation demonstrated by Tabuchi et al. With regard to determining the duration of the disease states set forth in claims 7-9 is obvious because it is a part of routine medical examination/diagnosis to find out the severity of the disease state and to determine optimum medical care that is necessary. Further, the affected loci within the inner ear membrane to be administered is obvious because tinnitus occurs in inner ear, therefore, one of ordinary skill in the art would directly to, in or to the vicinity of the inner ear in order to optimize the protection of cochlear damaged by ischemic-reperfusion. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
July 22, 2008